institute for radioelements

Fleurus, September 26th, 2019

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Chairman Kristine L. Svinicki
US Nuclear Regulatory Commission
Mail Stop 0-16 B33
Washington, D.C. 20555-001
USA

In the matter of :
US DEPARTMENT OF ENERGY
(Export of 93.35 % Enriched Uranium)
Docket N° 110-06361
License N°. XSNM3810

Subject : Justification of IRE's HEU export request

Dear Madam,

We have read the letters from NorthStar, Curium and the NTI requesting a hearing, and we have found that the arguments made are either not in accordance with the facts, or misinterpreting IRE's intentions. This letter is intended to clarify them.

Introduction

For over 40 years, the Institute for Radioelements (IRE) has been producing radioisotopes for the nuclear medicine. Specifically, IRE has Uranium targets irradiated in research reactors, which by fission produces many different radioisotopes.
IRE processes the targets to isolate and purify 3 specific isotopes, the Molybdenum 99 (^{99}Mo), Iodine-131 (^{131}I) and Xenon-133 (^{133}Xe). These isotopes come from the same process, and IRE has no means to produce 1 isotope without producing the others, as they are all a result of the fission of Uranium-235 in fixed proportions.
One should bear in mind that while the ^{99}Mo supply is ensured by several major producers, the ^{131}I supply in the US usually relies only upon 2 actors, IRE and NTP.

The new process development for LEU

The conversion of the process from using HEU as a source of uranium, to using LEU, has been a huge endeavour from IRE for many years, and it required heavy investments and many resources. Unlike other actors, IRE could not switch to LEU without completely changing the design of its targets, not only for technical reasons, but also because the Belgian regulator (FANC, standing for Federal Agency

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for Nuclear Control) took the opportunity of the conversion to LEU to have IRE design a new process, taking into account increased safety demands. The shape, the material encasing the uranium were changed, but also specific steps of the chemical processing. The result was a complete redesign of the process, that none of IRE's competitors had to undertake.

As IRE is extracting 3 radioisotopes, it had to redesign 3 extraction processes:

The separation and purification of ^{99}Mo

The capture of ^{133}Xe

The separation and purification of ^{131}I

For process reasons, the purification of the solution of ^{131}I could only be designed when the process of purification of the ^{99}Mo solution was finalized. This prevented IRE to develop both purification processes in parallel, and is the reason why, at this point in time, the ^{99}Mo purification process is validated while the ^{131}I process is not yet finalized.

The conversion to the ^{99}Mo produced from LEU will be possible for all IRE's customers when they have received approval from their respective pharmaceutical authorities. This point should be reached at the end of 2020, and IRE has enough stock of HEU until then. Nevertheless, the conversion will not be possible as the customers will not yet be ready to convert to ^{131}I coming from LEU. This is due firstly because the pharmaceutical validation of LEU-based ^{131}I will only take place in the first half of 2020; and secondly because the drugs made with ^{131}I are so diverse, that some customers need almost 2 years to receive approval for all the registration files they have to submit.

Some claim that IRE could easily support the ^{131}I market with less than half a kilogram of uranium over 2 years. This is absurd, as the ^{131}I comes from the same fission process as ^{99}Mo. The day the HEU fission process is replaced by a LEU process, only 131I coming from LEU will be available.

Considering (i) that each gram of Uranium-235 generates approximately 5 Ci of ^{131}I at user calibration need , and (ii) that IRE supplies to the market 600 Ci each week, 2 years represent a need of over 12 kg of uranium.

<u>Reasons for delays in the conversion schedule</u>

An important constraint is that the development of the new processes was executed while maintaining routine production with HEU, to ensure the supply of the market. This was very constrained because:

(i) IRE facilities as well as human resources were split between the commercial production using HEU and the development or validation runs for the new LEU process, and .

(ii) IRE is depending , for both HEU production and LEU developments, from irradiation reactors, which do not always have additional capacity to accommodate all IRE's irradiation requests

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An additional reason for delay was that NTP, the South African producer of ^{99}Mo and ^{131}I, has been down since November 2017 for safety reasons. NTP resumed at 40% capacity its ^{99}Mo production in March 2019, and at the same rate its ^{131}I production early September 2019. During all this period, the Australian producer of ^{99}Mo had several shutdowns, for safety and technical reasons during several periods. The last period started early July 2019 and will probably last until the end of the year. Because of these unexpected shutdowns, IRE had to run at full capacity all the time, making the allocation of resources even more difficult, causing delay in the development of the LEU solution, and consuming more HEU fuel, depleting IRE's stock.
In such circumstances, IRE cannot but adhere when, at competitor or customer request, reactors privilege run production in lieu of IRE's validation run for LEU.
IRE has been supporting 30 to 40% of the US market with ^{99}Mo supply, and almost 100% of the ^{131}I drugs supplied to the US market use Iodine originally produced by IRE. When IRE's competitors claim that the US market is well supplied in ^{131}I, they are right, but it is because IRE has taken over the part of the volumes originally supplied by NTP.

Proliferation risk

IRE acknowledges that the use of HEU represents a proliferation risk, and has deeply committed many years ago to start a long and expensive conversion process. Although we request a last export licence, this export does not increase the proliferation risk significantly. All actors involved in our supply, from Framatome for the making of the targets, to the research reactors irradiating them, and IRE doing the processing, have very high Security standards, which fissile materials accountancy is closely controlled by AIEA . These standards have even been improved in the past years. All these companies are frequently inspected by the NNSA to make sure that they comply with the highest Security standards.

We feel that IRE should not be punished to have supported the worldwide market of ^{99}Mo and ^{131}I, and more specially the US, when NTP and ANSTO were failing to do so. This situation has caused the depletion of stock of HEU, and added delays to the development of new processes that were already a challenge to keep on track.

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Conclusion

IRE does not contribute at all to nuclear proliferation and always shows its strong effort to LEU conversion, carefully balanced, as demonstrated above, against ensuring reliability of supply to the medical community and more particularly to the US market.
IRE, in this respect, committed that this licence request would be the last.
Should that licence not be granted, the supply of ^{131}I would be at risk even if no shortages in the supply of ^{99}Mo are expected. The ^{131}I supply for the US market relies indeed upon 2 actors, IRE and NTP. As NTP has met production issues in recent years, and has only resumed 40% of its original ^{131}I production since early September, the denial of the export licence would definitely represent a serious supply risk to the US.

We remain at your entire disposal for any question you may have.

Yours Sincerely,

Erich Kollegger
CEO

Copy : Secretary, U.S. Nuclear Regulatory Commission

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